

Appendix A

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Comments on Prior Art

Sunn W., et al., Methods and Apparatus for Discriminating P and R Waves, US Patent 5,778,881 (Jul. 14, 1998).

A wavelet transform (discrete) of an ECG or implanted device EGM segment is taken, reduced in length to encode the salient data (either through amplitude or index discriminators) and fed into a Hidden Markov Model (HMM). This HMM is then used to detect and differentiate the specific waves and arrhythmic events in terms of state sequences and observation sequences (as used extensively in natural language processing). Conventionally, the ECG is simply decimated into segments and analysed. This invention, therefore, uses the wavelet transform coefficients to encode the data and so increase the system's effectiveness and reduce its computational complexity.

Thus, this method uses WT's for data encoding, it is applied to sinus rhythm for detection of salient features and rhythm abnormalities. We would suggest, therefore, that this invention employs different types of wavelets on a different rhythm to achieve a different goal to our method. Subsequent to our omission of Claims 34 and 35 (the application of a wavelet transform to an ECG), we feel there is no longer any relationship or overlap between this patent and our patent application.

Duong-Van M., Method of Quantifying Cardiac Fibrillation Using Wavelet Transform, US Patent 5,439,483 (Aug. 8, 1995).

For this patent a Mexican hat like function is used on a 2 second window of ECG. The described use is for implanted cardioverter/defibrillator (ICD). The goal of the invention is to quantify the seriousness of fibrillation and so to identify the degree of shock necessary. This should optimise the usage of the ICD's battery so lengthening its useful life and reduce patient discomfort i.e. it is specifically for ICD's. However, the inventor also states the scope of the invention may be extended for use in external defibrillators. The methodology involves a comparison of QRS peaks in the recorded data with that which is expected i.e. the number of recorded peaks is subtracted from the number in a pre-VF trace segment. The larger the number the more serious the VF episode and the higher the shock required.

The entire method associated with this patent requires that QRS complexes be present. Indeed it may be argued that, by only looking for these complexes, this method does not analyse VF at all, but rather describes how 'sinus-like' the EKG is. For the general case, longer term VF containing no complexes

is most likely. Consequently, the described method of peak picking will not work - it will simply characterise every VF episode as being that of the most serious type. Also, for automated external defibrillators, it is very unlikely that any pre-VF sinus rhythm would be recorded to allow the base 'peak count' necessary for this method. Our methodology uses neither temporal peak picking techniques nor previously knowledge of the presented patient's EKG; rather our system classifies a presented trace based on previous 'experience' gained during its developmental stages. Importantly, this 'missing peaks' step is contained in each claim describing the invention's methodology. Subsequent to our omission of Claims 34 and 35 (the application of a wavelet transform to an ECG), we feel this patented method is in no way akin to our presented method.

Sun H.H., et al., System and Method for Analysing Electrogastrophic Signal, US Patent 5,795,304 (Aug. 18, 1998).

This patent's method and system is employed in analysing an electrogastrophic (EGG) signal. A continuous wavelet transform is used to analyse non-stationary body signals due to its known advantages over contemporary Fourier techniques. The method is used to de-couple low frequency 'slow waves' (<0.15Hz) from intermittent, high frequency, 'spike activity' (0.15-0.2 Hz). EKG signals are filtered using either an IIR or FIR filter before the transform is applied. The frequency of peak amplitudes at any given time in the transform space is then given to be indicative of the presence or otherwise of spike activity.

Intrinsic to this patent is the filtering of all cardiac data and its removal as noise. Subsequent to our omission of Claims 34 and 35 (the application of a wavelet transform to an ECG), we feel there is no longer any relationship or overlap between this patent and our patent application.

Keselbrener L., Apparatus and Method for Time Dependent Power Spectrum Analysis of Physiological Signals, Patent WO 96 08992 (Mar. 28, 1996).

The apparatus and method described by this patent is employed in the time dependent power spectrum analysis of a physiological signal modulated by the autonomic nervous system (ANS). Wavelet methods are quoted as one of those that may be used to obtain a time-frequency spectrum without assuming stationarity (or quasi-stationarity) within the analysed signal. Specifically, the method is used to provide information associated with the functioning of the autonomic nervous system from the ratio of high and low frequency energies in the derived power spectrum. Thus an indication of the relative influences of the parasympathetic (high and low frequency components) and sympathetic (low frequency

components only) systems on the subject's response to stimulation is produced.

The fibrillating myocardium does not form part of the autonomic nervous system and no claim is made in the above patent to suggest such. No method describing specific wavelet types or implementation is presented and none of our analytical methods are employed in the above patent. Subsequent to our omission of Claims 34 and 35 (the application of a wavelet transform to an ECG), we feel there is no longer any relationship or overlap between this patent and our patent application.

Millet-Roig J. et al., Study of Frequency and Time Domain Parameters Extracted by Means of Wavelet Transform Applied to Distinguish between VF and other Arrhythmias, Database Inspec [Online] Institute of Electrical Engineers, Stevenage, GB, 9/13/98, XP002145546.

A decimated, dyadic, discrete, wavelet transform is applied to an ECG and statistical methods used on the resultant coefficients to discriminate between the types of presented trace. In all of our claims pertinent to a fibrillating heart we have assumed knowledge the patient's type of arrhythmia. Our invention does not lie in the discrimination of arrhythmia type, but rather a method of determining the best therapeutic intervention for the presented patient. Subsequent to our omission of Claims 34 and 35 (the application of a wavelet transform to an ECG), we feel there is no longer any relationship or overlap between this paper and our patent application.

Chen J. et al., ECG Compression by Using Wavelet Transform, IEICE Transactions on Information and Systems, JP, Institute of Electronics Information and Comm., Eng. Tokyo, E76-D (12): 1454-1461 (1993).

A decimated, dyadic, discrete, wavelet transform is applied to an ECG and a quantizer and entropy encoder used to compress an ECG for digitised transmission or storage. The goal and methodology of this research is therefore completely different to the invention and methodology of our patent. Subsequent to our omission of Claims 34 and 35 (the application of a wavelet transform to an ECG), we feel there is no longer any relationship or overlap between this paper and our patent application.

Geva A.B., Spatio-Temporal Matching Pursuit (STOMP) for Multiple Source Estimation of Evoked Potentials, Database Inspec [Online] Institute of Electrical Engineers, Stevenage, GB, 11/5/96, XP002145547.

This paper is specifically concerned with the estimation of a 3D model for mass neural activity using multiple source EEG and MRI data and Spatio-Temporal Matching Pursuit methods. An exhaustive search for correlation within the decomposed data is used to produce such a model. It is recognised, however, that this STOMP decomposition algorithm may be applied for other sensor-array inverse problems like ECG source estimation. No such inverse engineering would be possible for a fibrillating myocardium where electrical activity is highly uncoordinated. These facts notwithstanding, Claim 33 (the matching pursuit claim) has been removed due to the lack of methodological steps presented in the description.

Sava H., et al., Application of the Matching Pursuit Method for Structural Decomposition and Averaging of Phonocardiographic Signals, Medical and Biological Engineering and Computing, GB, Peter Peregrinus Ltd, Stevenage, 36 (3) 302-308 (1998).

A matching pursuit method is used to locate specific heart sounds within a phonocardiogram. The direct identification and location of PCG features enables the synchronisation of cardiac cycles for signal averaging without the need for additional ECG's and QRS detection (usually recorded in parallel to enable this synchronisation). The PCG signal is an acoustic signal revealing different features to an ECG (valve function rather than electrical activity). It is also noted that the signal in question is sinus rhythm rather than a fibrillating myocardium. Fibrillation can not be analysed using PCG due to the lack of heart sounds. These facts notwithstanding, Claim 33 (the matching pursuit claim) has been removed due to the lack of methodological steps presented in the description.